



NOV 29 2000

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your continued interest in the reuse of medical devices that are labeled for single use. This is in response to your letter of November 1, 2000, co-signed by Chairman Fred Upton, Subcommittee on Oversight and Investigations, Committee on Commerce, requesting answers to questions pertaining to the Food and Drug Administration's (FDA or the Agency) policy with regard to the reuse of medical devices labeled for single use. Your questions will be re-stated, followed by our response. A similar letter has been sent to Chairman Upton.

1. What is the review standard that FDA intends to use to review 510(k)s and PMAs submitted by reprocessors?

FDA's review "standard" requires that an applicant's premarket submission demonstrate: (1) (for a 510(k)) that the device is "substantially equivalent" in all respects, not just intended use, to a legally-marketed device; or (2) (for a premarket application [PMA]) that there is a reasonable assurance that a device is safe and effective for its intended use(s). The Agency's review of all premarket submissions is based on valid scientific evidence, applicable laws and implementing regulations, and relevant guidance documents and technical standards. Premarket evaluation for class III devices includes not only a technical assessment of device performance but a quality systems assessment of the manufacturing process. For reprocessed devices subject to 510(k) requirements, FDA intends to maintain a high priority for quality systems assessments.

2. Will the FDA apply the same standards FDA uses for devices reused one time to devices reused multiple times?

Yes, FDA will apply the same review standards for all medical devices submitted for premarket evaluation, whether from original equipment manufacturers or reproprocessors, because the Agency considers reproprocessors of devices labeled for single use to be manufacturers. The Agency's final guidance on reuse of single-use devices (SUDs) clarifies that all regulatory requirements for manufacturers also apply to third-party and hospital reproprocessors of devices intended for single use.

A manufacturer can market a device for one more single use from a raw material that was a previously-used, SUD if that device meets the specifications of the device described in the marketing clearance. Compliance with quality systems requirements will assure that the device that is marketed for one more use meets the specifications described in the 510(k).

There will be different information requirements for a device that is intended for multiple uses by the end user. Submissions for a device intended to be reused multiple times will need to include information to establish that the device can be reused by the end user, and may include validated instructions for cleaning, disinfection, or sterilization. This is the Agency's current requirement for all manufacturers of reusable products and it is the same standard the Agency intends to apply to third-party and hospital reproprocessors that reprocess for multiple use devices originally intended for single use.

3. How do FDA's review standards on reuse protect patients who have devices used on them that have been reused more than once?

The premarket review process protects all consumers. In this case a reprocessed, previously used, SUD could not be marketed for patient use if the finished device fails to meet specifications that the reproprocessor established, and that FDA reviewed and cleared or approved. A premarket review conducted under the review "standards" described above results in clearance or approval of a device with critical design and performance specifications. These design and performance

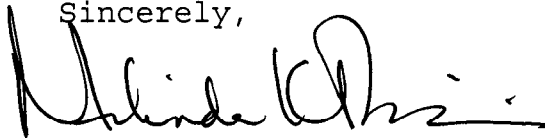
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specifications are intended to ensure the device is substantially equivalent to other devices of the same type in commercial distribution (for 510(k) devices), or is reasonably safe and effective for its intended use (for PMA devices). The manufacturer must ensure that these specifications are met whether the device is intended for one-time use or multiple uses.

In addition, the quality system requirements (Title 21, Code of Federal Regulations Part 820) set mandatory standards to ensure that devices are properly and consistently manufactured. FDA is confident that our inspectional processes will help identify reproprocessors who do not comply with current good manufacturing practices.

Thank you again for your continued interest in this issue. If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Melinda K. Plaisier". The signature is fluid and cursive, with a long horizontal stroke at the end.

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce

The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight
and Investigations
Committee on Commerce